IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION

OAK HILL HOMETOWN PHARMACY

Petitioner,

v. CIVIL ACTION NO. 2:19-cv-00716

UTTAM DHILLON, et al.,

Respondents.

RESPONDENT'S CLOSING STATEMENT IN OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER

I. THE TEMPORARY RESTRAINING ORDER STANDARD

A temporary restraining order ("TRO") is an extraordinary remedy involving the exercise of very far-reaching power to be granted only sparingly and in limited circumstances. *See MicroStrategy, Inc. v. Motorola, Inc.*, 245 F.3d 335, 339 (4th Cir. 2001). It seems the parties agree that a movant seeking a TRO must establish: (1) a likelihood of success on the merits; (2) irreparable harm in the absence of preliminary relief; (3) that the balance of equities tips in the party's favor; and (4) that the injunction is in the public interest. *Winter v. Natural Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *Pashby v. Delia*, 709 F.3d 307, 320 (4th Cir. 2013). Each of these four elements must be independently satisfied in order for a TRO to issue. *See Winter*, 555 U.S. at 20; *Pashby*, 709 F.3d at 320. A failure to establish any of the elements necessary for relief is fatal to the request for a TRO or preliminary injunction. *See Winter*, 555 U.S. at 20; *Pashby*, 709 F.3d at 320.

II. THE PETITIONER IS NOT LIKELY TO SUCCEED ON THE MERITS

The Drug Enforcement Administration ("DEA") determined that to allow Oak Hill Hometown Pharmacy ("OHHP") to dispense Subutex and other controlled substances while the

Agency pursues administrative revocation of OHHP's registration would pose an "imminent danger to public health or safety." 21 U.S.C. § 824(d); 21 C.F.R. § 1309.44. Thus, the DEA issued an Immediate Suspension Order ("ISO") on August 6, 2019. (*See* ECF No. 1-2.) OHHP is seeking to enjoin the DEA from enforcing the ISO by asking for a TRO.

A. The merits of this case must be reviewed under the arbitrary and capricious standard.

A court of competent jurisdiction reviews a determination by the DEA of "imminent danger" under an arbitrary and capricious standard. *See Cardinal Health, Inc. v. Holder*, 846 F. Supp. 2d 203, 214 (D.D.C. 2012); *Holiday CVS, L.L.C. v. Holder*, 839 F. Supp. 2d 145, 158 (D.D.C.), *vacated and remanded on other grounds*, 493 F. App'x 108 (D.C. Cir. 2012) (per curiam); *Novelty Distribs., Inc. v. Leonhart*, 562 F. Supp. 2d 20, 29 (D.D.C. 2008) (noting in a challenge to an § 824(d) suspension that "the underlying question on the merits is whether DEA acted arbitrarily and capriciously in suspending [Plaintiff's] registration based on a preliminary finding that its continued operation posed an 'imminent danger to public health or safety'").

The standard of review to be used by a reviewing court is set forth in the Administrative Procedure Act. *See* 5 U.S.C. § 706. The Court should only set aside the DEA Administrator's decision if it is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." § 706(2)(A); *see also MacKay v. DEA*, 664 F.3d 808, 817 (10th Cir. 2011) (reviewing the DEA Administrator's decision to revoke a doctor's registration to dispense controlled substances). Such a standard is "highly deferential, with a presumption in favor of finding the agency action valid." *King v. Burwell*, 759 F.3d 358, 373 (4th Cir. 2014) (quoting *Ohio Valley Envtl. Coal. v. Aracoma Coal Co.*, 556 F.3d 177, 192 (4th Cir. 2009)). Thus, "[a] court 'is not to substitute its judgment for that of the agency.'" *Akhtar-Zaidi v. DEA*, 841 F.3d 707, 710–11 (6th Cir. 2016)

(per curiam) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)).

OHHP urges the Court to conclude that a *de novo* review of the DEA Administrator's decision is the appropriate standard. OHHP relies on the Supreme Court's statement in *Camp v. Pitts* that "de novo review is appropriate only where there are inadequate factfinding procedures in an adjudicatory proceeding. . . ." 411 U.S. 138, 142–43 (1973) (per curiam). However, the Court went on to hold that the only deficiency suggested was that the agency inadequately explained its decision and that any such failure, if it occurred, was not a deficiency in factfinding procedures such as to warrant a de novo hearing . . . ." *Id.* (vacating the appellate court's review of the agency's decision because it inappropriately applied a *de novo* standard when it should have applied the arbitrary and capricious standard set forth in the APA, § 706(2)(A)). OHHP argues that the basis for the ISO was not adequately explained or supported. As will be discussed below, this is demonstrably wrong. But even if one assumes, arguendo, that the DEA's fact finding was inadequate here, it would not constitute a deficiency warranting *de novo* review. *Camp*, 411 U.S. at 142–43; s*ee also Cardinal Health, Inc.*, 846 F. Supp. 2d at 229–30 (rejecting Cardinal's argument that due process requires a *de novo* review of imminent danger because such a "reading is inconsistent with the plain meaning of the statute" and "Congress did not grant th[e] Court the power to substitute its own judgment regarding the existence of an imminent danger for the judgment of the Administrator").

The standard for reviewing the ISO is the arbitrary and capricious standard. A *de novo* review is not appropriate under the circumstances presented here. In addition, in applying the arbitrary and capricious standard, the focus of judicial review must be the administrative record, not some new record made initially in the reviewing court. *See Camp*, 411 U.S. at 142. This

holding forbids "*ex post* supplementation of the record by *either side*." *Walter O. Boswell Mem. Hosp. v. Heckler*, 749 F.2d 788, 793 (D.C. Cir. 1984) (emphasis added); *see IMS, P.C. v. Alvarez*, 129 F.3d 618, 624 (D.C. Cir. 1997) (rejecting the plaintiff's attempt to submit litigation affidavits to supplement the agency record *ex post*); *AT & T Info. Sys., Inc. v. Gen. Servs. Admin.*, 810 F.2d 1233, 1236 (D.C. Cir. 1987) (rejecting agency's attempt to submit litigation affidavit to provide *post hoc* rationalization of the agency's action).

B. Diversion of Subutex poses an imminent danger.

The actual or potential diversion of Subutex poses an imminent danger to the public health or safety. The DEA has classified all buprenorphine products, including Subutex, as Schedule III controlled substances. This alone demonstrates that it is a dangerous drug, subject to diversion and abuse. In addition, Subutex is approximately 20 to 30 times more potent than morphine as an analgesic. (*See* ECF No. 7-2.) Like morphine, Subutex produces dose-related euphoria, drug liking, papillary constriction, respiratory depression, and sedation. (*Id.*) Like other commonly abused opioids, buprenorphine is capable of producing significant euphoria. (*Id.*) Indeed, data indicate that Subutex has been abused by various routes of administration (sublingual, intranasal, and injection) and has gained popularity as a heroin substitute and a primary drug of abuse. (*Id.*) The potential for diversion and abuse of Subutex in particular has led a number of states, which have been significantly impacted by the opioid crisis and are contiguous to West Virginia, to prohibit the prescribing of Subutex, except in those circumstances where naloxone (included in Suboxone) will harm a patient (i.e. pregnancy and/or a naloxone allergy). Among these states are Kentucky, Ohio, and Virginia. *See* 201 Ky. Admin. Regs. 9270; Ohio Admin. Code 4731-33-03; 18 Va. Admin. Code § 85-21-150.

Furthermore, the pharmacy expert consulted by the DEA opined that because Subutex is an opioid derivative, it poses a significant risk of abuse and diversion. *See also United States v. Walker*, No. 2:17-cr-00010, 2017 WL 2766452, at *2 (S.D. W. Va. June 26, 2017) (Goodwin, J.) (discussing the defendant's history of abusing illicit drugs, including his misuse of Subutex beginning around age twenty-six). This specific opinion of the DEA's expert is set forth in the detailed findings made by the DEA Administrator in the ISO. (*See* ECF No. 1-2 at 3.) These are just some of the reasons why registered pharmacies, such as OHHP, must adhere to their legal responsibility to dispense controlled substances properly and to safeguard against diversion of controlled substances. 21 U.S.C. §§ 829, 841(a)(1), 842(a)(1); 21 C.F.R. § 1306.04.

C. DEA made detailed and specific findings that OHHP was dispensing Subutex in violation of the law.

1. DEA's expert opined that OHHP should not have filled Subutex prescriptions.

From at least December 2016 to March 2019, OHHP's pharmacists filled approximately 2,000 prescriptions for Subutex. (ECF No. 1-2 at 3.) The pharmacy expert indicated that buprenorphine is frequently combined with naloxone, which is an opioid antagonist that blocks or reverses the effects of opioids if the user attempts to abuse the drug. (*Id.* at 3–4.) The DEA's expert further indicated that Suboxone (a buprenorphine product that includes naloxone) has a lower abuse potential than buprenorphine-mono-products, like Subutex. Thus, he opined that Subutex should be prescribed as the first-line treatment for narcotic addiction, unless the patient is pregnant or allergic to naloxone. (*Id.*) Accordingly, the DEA's expert opined that a pharmacist should not fill a Subutex prescription unless the patient is pregnant or allergic to naloxone. (*Id.*) These are not unconventional or extreme opinions. In fact, the FDA has consistently approved product labeling, most recently revised this year, that includes the following language: "The use of SUBUTEX for unsupervised administration should be limited to those patients who cannot tolerate

SUBOXONE, for example those patients with known hypersensitivity to naloxone." SUBUTEX Medication Guide, Indivior Inc. (2019), *available at* https://www.accessdata.fda.gov/drugsatfda_docs/label/2018/020732s018lbl.pdf. As such, it was not arbitrary or capricious for the DEA to adopt the expert's opinion in the ISO.

Indeed, while not binding on this Court, it is noteworthy that federal district courts have specifically found that because Subutex does not contain naloxone, it is more subject to diversion and abuse than Suboxone and, therefore, the prescribing of Subutex is generally appropriate only if the patient is pregnant or allergic to naloxone. *See, e.g.*, *United States v. Palin*, No. 1:14CR00023, 2016 WL 5941930, at *2 (W.D. Va. Apr. 7, 2016) ("Findings of Fact. . . . 6. The naloxone hydrochloride ("naloxone") contained in Suboxone is a reversal agent that prevents users from experiencing a high if they take the medication other than as prescribed. Because Subutex does not contain naloxone, it is more subject to diversion and abuse than Suboxone. Therefore, prescription of Subutex is generally appropriate only if the patient is pregnant or allergic to naloxone."), *aff'd*, 874 F.3d 418 (4th Cir. 2017) (finding that the evidence at trial was sufficient to convict the defendants), *cert. denied*, 138 S. Ct. 1451 (2018), *cert. denied*, 138 S. Ct. 1605 (2018). Unsurprisingly, other states that have been dramatically impacted by the opioid crisis have taken steps to prohibit the prescribing and/or dispensing of Subutex except in those instances where the patient is pregnant or allergic to Suboxone (due to the presence of naloxone). *See* 201 Ky. Admin. Regs. 9270; Ohio Admin. Code 4731-33-03; 18 Va. Admin. Code § 85-21-150.

The opinions of the DEA's expert pharmacist played an important role in formulating the findings within the ISO. The expert's opinions were, on their face, reliable and supported by publically available information, data, and legal authorities. Moreover, the expert's opinions represent the only expert analysis before the DEA when the Administrator issued the ISO. The issue here is not whether the DEA should have considered other opinions or reviewed materials

that might have included contrary views. The issue is whether the DEA acted arbitrarily and capriciously in relying on the opinions of its expert. It did not.

2. The Subutex prescriptions at issue here displayed numerous "red flags."

The DEA made detailed and specific findings that all of the prescriptions addressed in the ISO presented no less than five red flags, each of which was an indication that the prescriptions should not have been filled. These findings were, according to the ISO itself, based on a careful review of OHHP's prescription drug monitoring program data ("PDMP data") obtained from the West Virginia Board of Pharmacy. (ECF No. 1-2 at 6.) In the context of prescriptions for controlled substances, a "red flag" is a sign or indication that there is a substantial risk of abuse or diversion of the prescribed drug. *Jones Total Health Care Pharmacy, LLC v. DEA*, 881 F.3d 823, 827–28 (11th Cir. 2018); Drug Enforcement Administration, *Pharmacists Manual: An Informational Outline of the Controlled Substances Act*, 30 (2010), https://www.deadiversion.usdoj.gov/pubs/manuals/pharm2/pharm_manual.pdf. (*See also* ECF No. 1-1 at 3.)

It is widely recognized that pharmacists are supposed to be aware of and looking for red flags so as to avoid filling prescriptions for controlled substances that were or may have been written for other than legitimate medical purposes, including:

> Prescriptions written by doctors whose offices are a great distance from the pharmacy; . . . [t]he patient seeking to fill the prescription lives far away from the prescribing physician; . . . [a] large percentage of the prescriptions presented at the pharmacy originated from the same doctor; . . . [t]he payment method is cash rather than a credit card; . . . [a] line forms at the pharmacy, with each patient in the line presenting a prescription written by the same physician; . . . [and a] large percentage of prescriptions presented at the pharmacy are for controlled substances, as opposed to medications that are not controlled[.]

Mark Rosenblum, *Opioid Epidemic*, Crim. Just., Winter 2019, at 12. The more red flags presented on a frequent basis, the more likely it is that the pharmacist, whether purposefully or unwittingly, has become part of the drug diversion chain. *Id.*

The red flags delineated above are among those specifically found by the DEA in the ISO's findings of fact. Red flags that were routinely and repeatedly associated with the prescriptions presented at OHHP included, but were not limited to, the following:

1. The prescriptions were for Subutex (a buprenorphine-mono-product), a widely abused controlled substance.

2. The prescriptions were written by prescribers outside of West Virginia.

3. Approximately 96% of the prescriptions were paid for with cash.

4. The patients/customers, who resided in southern West Virginia, traveled great distances to Western Pennsylvania to obtain the prescriptions.

5. Most of the patients/customers traveled a significant distance to have the prescriptions filled at OHHP, and in doing so, eschewed pharmacies much closer to their homes.

6. Many of the prescriptions were not filled entirely at the first presentment. Instead, OHHP routinely filled the prescriptions piecemeal over multiple visits.

7. The Pennsylvania prescribers in question appeared to be "pattern prescribing."

(ECF No. 1-2 at 3–8.) It is clear that unresolved or unresolvable "red flags" are important indications of diversion, especially when there are multiple. The ISO amply discusses multiple red flags that were ignored by OHHP.

3. <u>DEA compared prescribing habits of Pennsylvania and West Virginia prescribers.</u>

The analysis of PDMP data included in the ISO demonstrates very troubling prescribing trends that were readily apparent to OHHP. The PDMP data, which records all of the controlled substance prescriptions that OHHP filled, showed that Pennsylvania medical professionals

prescribed Subutex much more frequently than West Virginia medical professionals. (*Id.* at 6.) Out of the over 2,000 buprenorphine prescriptions that OHHP received from Pennsylvania prescribers, approximately 97% were for Subutex, while only 3% were for Suboxone. (*Id.*) The DEA's expert opined that a ratio of 97% Subutex prescriptions to 3% Suboxone prescriptions is highly suspicious and indicates that these prescriptions were not issued for a legitimate medical purpose. (*Id.*) During this same time frame, only 2% of buprenorphine prescriptions that OHHP received from West Virginia prescribers were for Subutex, while the remaining 98% were for Suboxone. (*Id.*) The DEA's expert opined that OHHP's southern West Virginia customers appeared to be seeking out medical professionals in Pennsylvania because they were willing to prescribe Subutex, which is easier to abuse and divert than Suboxone (buprenorphine/naloxone). (*Id*.) This is a significant finding based on evidence (the PDMP data) that was before the DEA and is before the Court, (Pet'r Ex. 1 at Tab 20), and consultation with the DEA's expert.

4. DEA identified and offered specific findings of pattern prescribing.

The DEA's expert opined that "pattern prescribing" is a red flag of abuse and diversion for which pharmacists must monitor. (ECF No. 1-2 at 7–8.) Pattern prescribing describes a physician who prescribes widely-abused drugs, often in the same dosages and quantities, to many patients. (*Id*.) Pattern prescribing is a red flag of abuse and diversion because it indicates that the physician is focused on distributing drugs with high street value rather than on examining his patients and developing individualized treatment. (*Id*.) *See also United States v. Akers*, No. 7:19-CR-7-REW-EBA, 2019 WL 4934948, at *3, 9 (E.D. Ky. Oct. 7, 2019). OHHP repeatedly filled prescriptions written by physicians who were pattern prescribing. (ECF No. 1-2 at 7–8.) For instance, one example offered by the DEA in the ISO provided that on October 13, 2018, four patients (Patients B.C.1., R.C., M.L.H., and C.S.) filled Subutex (a buprenorphine-mono-product) prescriptions at

OHHP that they had all received from Prescriber F.K. on the same day. (*Id*. at 7.) Prescriber F.K. worked at A&R Solutions in Pennsylvania, which is approximately 180 miles northeast of OHHP. (*Id*.) The occurrence of multiple patients presenting prescriptions to OHHP that had been written on the same day, by the same prescriber, at the same clinic, for the same drug, at the same dosage and quantity, was frequent. (*Id*.) This is another significant finding based on evidence (the PDMP data) that was before the DEA and is before the Court, (Pet'r Ex. 1 at Tab 20), and consultation with an expert.

5. OHHP customers traveled long distances to obtain prescriptions in Pennsylvania and secure partial fills at OHHP.

DEA found that a majority of these patients traveled long distances to fill their Subutex (a buprenorphine-mono-product) prescriptions at OHHP. (ECF No. 1-2 at 3–4.) Approximately 60% lived 30 or more miles from OHHP, and approximately 35% lived 50 or more miles from OHHP. (*Id*.) The DEA's expert opined that it can be a red flag of abuse and diversion if a patient travels a significant distance to a specific pharmacy, especially if the patient also travels a significant distance to a particular prescriber. (*Id*.) The DEA's expert also indicated that OHHP's customers made frequent partial fills of their prescriptions. (*Id*.) The DEA's expert opined that obtaining partial fills can be a red flag of abuse and diversion, especially when customers are purchasing a drug with a high street value, paying in cash, and traveling long distances to obtain and fill their prescriptions. (*Id*.)

One of many examples of a patient who traveled a long distance to her prescribers' offices and to OHHP and obtained multiple partial fills of each prescription is patient N.J. (*Id.*) From December 2016 to November 2018, Patient N.J. obtained 26 Subutex (buprenorphine-mono-product) prescriptions from six different prescribers at A&R Solutions, whose offices were as far as 180 miles northeast of her home. (*Id.*) Patient N.J. filled these prescriptions at OHHP, which

is approximately 50 miles southwest of her home. (*Id*.) She made the 100-mile round trip drive to OHHP 139 times during this timeframe to obtain partial fills of these prescriptions, and she always paid in cash. (*Id*.) Patient N.J. obtained up to seven partial fills per prescription, meaning that she traveled up to 1,000 miles to obtain and fill each prescription. (*Id.*) Again, this is a significant finding based on evidence (the PDMP data) that was before the DEA and is before the Court, (Pet'r Ex. 1 at Tab 20), and consultation with the DEA expert.

6. The factual findings in the ISO were not refuted by the testimony offered at the TRO hearing.

The DEA has objected to consideration of evidence offered months after the ISO was issued. Nonetheless, the DEA feels compelled to address some of the evidence briefly. The evidence that OHHP offered during the hearing does not even begin to resolve any, let alone all, of the red flags and anomalies. OHHP's witness, Lydia Sanford, testified that some of the patients had unverified reasons for traveling substantial distances to see providers in Pennsylvania, filling prescriptions at OHHP, and/or using cash. However, even if her testimony is taken at face value, it fails to address the multiple red flags associated with the thousands of prescriptions for Subutex filled at OHHP. In fact, she acknowledged that she volunteered to DEA investigators, in response to certain questioning, that some patients (not necessarily OHHP customers) prefer Subutex because it can be easily diverted and sold on the street and that it has a street value.

OHHP's owner, Martin Njoku, did not offer any meaningful explanation for the multiple red flags. OHHP's proffer relating to Mr. Charles Selby is similarly unpersuasive. It seems Mr. Selby would disagree with some of the opinions of the DEA's expert and the DEA's findings, but there is no reason to deem Mr. Selby's conclusions definitive. Moreover, nothing he would have said refutes any of the findings in the ISO.

Thus, even if the Court decides to accept this evidence, it does not suggest that the ISO was arbitrary and capricious.

D. OHHP has not established that it is likely to suffer irreparable harm absent a TRO.

1. OHHP's claims of harm are speculative.

Equitable relief is an "extraordinary remedy that may only be awarded upon a clear showing that the plaintiff is entitled to such relief." *Winter*, 555 U.S. at 22. To obtain the extraordinary remedy of a TRO or preliminary injunctive relief, a plaintiff must show that it is likely to suffer irreparable harm if the petition is denied. *Pashby*, 709 F.3d at 328 (citing *Winter*, 555 U.S. at 20). "To establish irreparable harm, the movant must make a 'clear showing' that it will suffer harm that is 'neither remote nor speculative, but actual and imminent.'" *Mountain Valley Pipeline, LLC v. 6.56 Acres of Land*, 915 F.3d 197, 216 (4th Cir. 2019) (quoting *Stuller, Inc. v. Steak N Shake Enters.*, 695 F.3d 676, 680 (7th Cir. 2012)); *see also Marietta Mem'l Hosp. v. W. Va. Health Care Auth.*, No. 2:16-cv-08603, 2016 WL 7363052, at *3 n.2 (S.D. W. Va. Dec. 19, 2016).

In this case, OHHP alleges a number of economic harms that may occur should a TRO or a preliminary injunction not issue. However, OHHP's allegations are speculative. Indeed, OHHP is not prevented from serving customers and dispensing non-controlled prescription medications. Of course, OHHP may contend that opioids and other controlled substances were such a significant facet of its business that it cannot continue operations without the ability to dispense narcotics. This, however, would be a rather incriminating argument to make. If a registrant cannot continue to operate without dispensing controlled substances, then it is evident that the ISO was warranted.

During two days of hearings, OHHP offered little to substantiate the claims of irreparable harm. Lydia Sanford testified that OHHP has lost business because of the ISO, and she expressed her concern that OHHP would have to close. Mr. Njoku testified that he also believes OHHP

might close as a result of the ISO. The proffer relating to Mr. Selby included his opinion that a pharmacy cannot survive without a DEA registration. But all of these assertions are speculative. OHHP has had nearly three months to assess the precise impact of the ISO on the business, yet OHHP failed to offer balance sheets, revenue loss estimates, financials, or other information to demonstrate that the vague assertions of Ms. Sanford and Mr. Njoku are probative. Moreover, the testimony of Ms. Sanford and Mr. Njoku is manifestly self-serving in the absence of financial verification. In other words, OHHP's evidence is speculative at best.

2. OHHP's claims of harm are undercut by unexplained delays in seeking relief.

Furthermore, the ISO was served on OHHP on August 8, 2019. For unknown reasons, OHHP waited nearly two months to petition the Court for preliminary injunctive relief. It was an additional nineteen days before OHHP filed the motion seeking a TRO. Additionally, there is no indication that OHHP sought relief elsewhere. OHHP represented that it learned during an administrative prehearing conference in October that the Administrative Law Judge did not have the authority to enjoin or restrain the ISO. However, OHHP has not explained why it did not inquire about potential relief at the administrative level sooner. OHHP also failed to explain whether it has conferred with the DEA about modifying the ISO in some way.

Such delays and failures are evidence that swift relief is not needed. *See Quince Orchard Valley Citizens Ass'n, Inc. v. Hodel*, 872 F.2d 75, 79–80 (4th Cir. 1989); *see also Candle Factory, Inc. v. Trade Assocs. Grp., Ltd.*, 23 F. App'x 134, 138 n.2 (4th Cir. 2001) (per curiam); *Tough Traveler, Ltd. v. Outbound Prods.*, 60 F.3d 964, 968 (2d Cir. 1995) ("Delay alone may justify denial of a preliminary injunction."); *Pharmacia Corp. v. Alcon Labs., Inc.*, 201 F. Supp. 2d 335, 383 (D.N.J. 2002) (explaining that delay in seeking preliminary injunction "knocks the bottom out of any claim of immediate and irreparable harm"); *cf. Rovio Entm't Ltd. v. Royal Plush Toys, Inc.*,

907 F. Supp. 2d 1086, 1097 (N.D. Cal. 2012) ("Parties spurred on by the threat of or actual immediate irreparable harm [must] file for TROs as quickly as possible to head or stave it off.") (collecting cases); *Montrose Parkway Alts. Coal. v. U.S. Army Corps of Eng'rs*, 405 F. Supp. 2d 587, 600 n.4, 602 (D. Md. 2005) (denying the plaintiffs' motion for TRO and preliminary injunction and noting that the plaintiffs' delay of "nearly one month after the alleged irreparable harm occurred" seemed "to undermine their claim of irreparable harm").

For these reasons, Petitioner has not established the kind of irreparable harm that would justify the issuance of a TRO, and the motion should be denied.

E. The balancing of equities favors the DEA.

In considering the extraordinary remedy of an injunction or a restraining order, a court must balance the competing claims of injury and must consider the effect on each party of the granting or withholding of the requested relief. In exercising their sound discretion, courts of equity should pay particular regard for the public consequences. *Winter*, 555 U.S. at 24 (citations omitted); *Sterling Drug, Inc. v. Bayer AG*, 14 F.3d 733, 747 (2d Cir. 1994). Where the defendant is the Government, the Court may consider these final two factors together. *See Nken v. Holder*, 556 U.S. 418, 435 (2009).

As the party seeking relief, OHHP must show that the DEA would not be unduly harmed by the entry of a TRO or a preliminary injunction. However, OHHP fails to address the harm to the DEA if a TRO were to be issued. Congress expressly granted the DEA the authority under § 824(d) to suspend a registrant's authority to prescribe controlled substances when there is evidence of abuse or diversion. Courts have recognized that the government has a strong interest in enforcing the CSA and ensuring that controlled substances are not improperly diverted while the administrative proceedings before the DEA are pending. *See Cardinal Health, Inc.*, 846 F. Supp. 2d

at 230. There is a significant public interest in preventing the illegal diversion of prescription drugs, particularly in light of the extensive problem of prescription drug abuse in West Virginia. *Id*.

Restraining the ISO, even temporarily, would impair the ability of the DEA to enforce the Controlled Substances Act and prevent diversion. Of course, the DEA does not have a free hand. It has to establish that the ISO was issued to prevent imminent danger to the community. Here, the DEA has done so through the significant findings outlined herein.

F. A TRO is not in the public interest.

OHHP claims that it plays a vital role in the Oak Hill, West Virginia, community. However, there are no fewer than seven other pharmacies within five miles of OHHP. (ECF No. 7-2 at 86–87.) There is at least one chain pharmacy within a mile of OHHP. (*Id*.) Mr. Njoku identified this pharmacy as being a Walgreens. OHHP has not offered anything to show that the Oak Hill community will find it difficult to locate a pharmacy while the administrative process proceeds to its ultimate conclusion. In fact, it is noteworthy that the vast majority of the prescriptions at issue in this matter were presented by individuals who were not part of the Oak Hill community. (Pet'r Ex. 1 at Tab 20.) To the extent OHHP is suggesting that inconvenience to its customers demonstrates irreparable harm, the Court should reject this point. This argument is irrelevant because it does not show irreparable harm to OHHP. Instead, it implies some harm to third parties. *See Winter*, 555 U.S. at 20. In *Winter* the Court held that a plaintiff seeking a preliminary injunction must establish that *it*, not others, is likely to suffer irreparable harm in the absence of preliminary relief. *Id*; *see also Cardinal Health, Inc.*, 846 F. Supp. 2d at 213.

On the other hand, the DEA has set forth specific and substantial findings in the ISO that indicate OHHP's possession of a DEA registration poses an imminent danger to public health or safety. Subutex is a dangerous drug susceptible to diversion and abuse, and the findings in the

ISO demonstrate multiple red flags of diversion. The West Virginia community has been devastated by the opioid crisis. *See Walker*, 2017 WL 2766452, at *3–8 ("Cultural Context"). Subutex is an opioid. The public interest weighs in favor of allowing the DEA to enforce the law and regulate controlled substances.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 25, 2019, I electronically filed the foregoing **RESPONDENT'S CLOSING STATEMENT IN OPPOSITION TO PLAINTIFF'S MOTION FOR A TEMPORARY RESTRAINING ORDER** with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the following:

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